

**Submission to  
the Ontario Standing  
Committee on Social Policy**

**Regarding Bill 102**

**By the Ontario Chain Drug  
Store Association**

Toronto  
May 30, 2006

**EXECUTIVE SUMMARY**  
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**Situation:**

The Government of Ontario has tabled legislation and announced policy that would bring about sweeping changes to the province's prescription drug system. Bill 102 and the Minister of Health's attendant policy statements, if implemented, would have a significant impact on both the practice and the economics of pharmacy in Ontario. Some of these changes would be positive, and the Ontario Chain Drug Association (OCDA) applauds them. However, the overall effect of the legislation and new policies would be deleterious to Ontario pharmacy, and, as a result, to Ontario patients.

In order to avoid serious disruptions to pharmacy and to patient care, the OCDA is recommending a number of amendments to this bill. In addition we would like to offer this Committee, the Legislature and the Minister of Health our organization's cooperation and support in modifying Bill 102, to achieve the stated objective of establishing a more transparent and effective prescription drug system for Ontarians.

**Overall Economic Impact:**

Based on calculations provided by the government, the Ontario Pharmacists Association (OPA) and our members, the OCDA estimates that **the overall effect of Bill 102 will be to reduce pharmacy funding and reimbursement by approximately \$500 million per year**. This figure may be offset to some extent by government policy proposals, if and when implemented, but the impact this legislation, in its current form, would have on the practice and economics of pharmacy can only be called "grave".

In fact, as written, Bill 102 would put the future viability of pharmacy in this province at risk. Without amendments, we would expect Ontario to experience the **closure of pharmacies, reductions in store opening hours, pharmacy staff layoffs, increased dispensary wait times, and, of critical importance, reduced services, care and access for patients**.

**Private Sector Impact:**

As drafted and described, Bill 102 and the government's policy announcements will extend beyond the purview of the Ontario Drug Benefit program, and drastically reduce pharmacy reimbursement related to private sector drug plans. The OCDA believes this is an unintended consequence of the government's reform plans. Traditionally, government policy has maintained a clear separation

between compensation levels regulated on behalf of beneficiaries of the ODB program and those covered by private plans.

Given that the ODB program covers approximately 43% of drug benefit costs in Ontario, **if the anticipated government cost reductions were to be extended to the private sector, the negative impact on pharmacy would be roughly doubled.**

We would therefore request that the government ensure that it be made clear, both in the legislation and in policy statements, that the ultimate policies regarding drug price reductions, dispensing fees and inventory allowance apply strictly to the portion of business relating solely to ODB beneficiaries.

### **Positive Provisions:**

The Minister's vision for reforming Ontario's prescription drug system is not without positive elements. In particular, the OCDA strongly supports the announcement that, for the first time, pharmacists will be recognized and compensated for cognitive services – care that goes far beyond the dispensing of medications and improves patient health outcomes. This policy prescription, though not integrated in Bill 102, would be a welcome acknowledgment of pharmacists' growing role in front-line patient health management.

In addition, OCDA welcomes the Minister's promise (again, not a feature of the bill) to create a Pharmacy Council, to consult pharmacists in the continuing development of pharmaceutical and health policy.

### **Negative Provisions:**

The most serious problem with Bill 102 and its attendant policy announcements is the legislation's absolute prohibition of professional allowances by generic drug manufacturers. These allowances, called "rebates" in the bill, currently represent a major portion of the funding available to pharmacies to maintain operations, pay and train staff, upgrade technology and provide patient education. The bill would ban these allowances, which are negotiated in the free market by pharmacists and suppliers, and would not replace this funding with any other equivalent mechanism. The net effect would be to cut pharmacy funding by hundreds of millions of dollars per year, a simply unsustainable situation.

Other provisions, announced as policy changes, that would be harmful to pharmacy, and ultimately to patient care, include:

- Reducing pharmacy markups on drugs from 10% to 8%. According to OPA data, this would have a negative impact of more than \$112 million annually.

- Capping pharmacy markups on drugs at \$25 per prescription. According to OPA data, this would reduce pharmacy funding by some \$56 million per year. It would actually force pharmacies to take a financial loss each time they stock an expensive new drug (products costing more than \$312 per claim).
- Increasing dispensing fees by only \$0.46 per prescription. Dispensing fees have fallen far behind the rate of inflation and population growth, increasing by only 2% since 1993, and do not cover the straight cost of dispensing medicines.

### **Recommendations:**

The OCDA's submission contains a number of recommended amendments both to Bill 102 and to the associated policy announcements. The effect of these proposed changes would be to limit the negative impact of the government's plans to pharmacy and patient care.

More broadly, the essence of the OCDA's recommendations is to acknowledge the following realities:

- Ontario's population is growing and aging.
- The role of prescription medicines in health care is increasing, requiring more, not less, involvement of pharmacists in patient health management.
- Pharmacists are being asked to expand their roles in primary care, and to increase levels of service and care to patients.
- Pharmacists are a key resource in health care cost control on the front lines, in appropriate medication use and in patient education.
- Pharmacy is both a health care profession and a business.
- It is not sustainable, or even possible, to demand more from pharmacists, while drastically reducing the funding that makes it possible for them to maintain and expand operations and care.

In summary, it is imperative that the Government of Ontario make appropriate amendments to Bill 102 before the passage of the legislation. In addition, the Minister of Health must review and revise certain stated policy intentions with respect to pharmacy funding. These steps are required in order to ensure the continuing health and effectiveness of pharmacy in Ontario.

## The OCDA:

Ontario's pharmacies and pharmacists, through the OCDA and related organizations, can play a vital role in assisting the government to deliver on its health agenda. Indeed, given the shortage of physicians and nurses in many areas in the province, and the requirements for decentralized health care delivery beyond traditional institutional and physician office settings, the government's goals can **only** be met with significant pharmacy involvement.

At the same time, OCDA recognizes the need for change within the current pharmacy compensation and drug listing policies. We want to work with the government, as a full partner, to ensure that these changes can be implemented in ways that will not unintentionally undermine the viability of the sector and thereby compromise our ability to help the government meet its objectives.

Pharmacy and pharmacists are not fully utilized in the health system and are open to working with the Ontario government to design and implement changes that will advance health system reform, reduce costs and contribute to economic growth.

- The Ontario Chain Drug Association is the voice of community pharmacy in Ontario. The 15 members of OCDA represent traditional chain drug stores (national and regional), banner groups (including independently owned and operated local pharmacies), grocery chains and mass merchandisers with pharmacies.
- OCDA members operate approximately 80% (2,285 stores) of community pharmacies in Ontario, employ approximately 39,270 Ontarians, including 5,333 or over 70% of licensed community pharmacists and 7,147 pharmacy technicians in the province.
- 1.6 million people visit a community pharmacy in Ontario every day.
- Community pharmacies are one of the most accessible health care providers, located close to where people live and work and alongside other primary health care providers in every community across the country.

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## **Background:**

On April 13<sup>th</sup>, 2006, the Minister of Health tabled Bill 102, the “**Transparent Drug System for Patients Act, 2006**”. The bill was referred to as the “cornerstone” of “a comprehensive plan to reform Ontario’s drug system”. While some of the announced policy intentions associated with this plan would, if implemented, have the effect of increasing transparency and consultation with stakeholders, the primary economic effect of the legislation itself would be to reduce costs under the budget of the Ministry of Health. This would result from two main initiatives: the complete elimination of professional allowances negotiated between pharmacies and generic drug manufacturers; and the increased use of generic pharmaceuticals, through the increased interchangeability of prescription medicines.

The Minister has also made a number of policy announcements, which would affect pharmacy, brand name and generic pharmaceutical manufacturers, physician prescribing and patients. For the purposes of this submission, the OCDA will focus primarily on the legislative and policy proposals affecting pharmacy.

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## **Legislation versus Policy:**

Since Bill 102 was tabled, we have noted that there exists a high level of confusion, not only among pharmacists, but also among the public at large, with respect to provisions that are part of the legislation and policy provisions that the Minister has announced as government intent.

For example, we have been asked by our members and by Ontario independent pharmacists if measures such as the establishment of a Pharmacy Council and the initiative to begin compensating pharmacists for cognitive services would in fact become law. We have responded to such inquiries, based on legal analysis, that these concepts are not part of the bill. Instead, they have formed part of the Minister’s announced policy changes affecting the drug system. This is an important distinction, because policy statements or promises do not have force of law. Moreover, policy can be changed at will by a current or a future government, without the process and scrutiny required with legislation. For the purposes of this submission, the OCDA will therefore deal separately with Bill 102 and the Minister’s policy statements.

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## Drug System Reform Process:

The OCDA wishes to note a number of concerns with respect to how the government proceeded in devising its plan to reform the Ontario drug system.

First, this is a sweeping plan that would have both broad and deep implications for all stakeholders and beneficiaries of the system. Given the size and complexity of the system, and of its importance to health care in Ontario, we believe that the government should have proceeded in a more considered, methodical and transparent fashion in drafting Bill 102 and the new policies.

For example, though the government states that it consulted more than 200 health stakeholders in preparation for launching its new plan, the public has not had access to the content of those consultations. **No report on those consultations has been publicly released by the Drug System Secretariat (DSS)**, which undertook the stakeholder meetings. In short, we do not know what stakeholders, ranging from pharmacists, to doctors, patients and drug manufacturers, told the DSS.

What we do know is that **the government did not consult stakeholders with regarding the specific provisions that appeared in the bill**, or regarding some of the subsequent policy announcements. As a result, stakeholders, including pharmacy, were surprised and unprepared when those provisions were unveiled. This is not a process that engenders confidence in an exercise that it promoted as one that increases “transparency”.

In addition, the government has formulated and announced this far-reaching plan without releasing any independent impact analyses. It would seem logical and responsible, when undertaking such extensive changes to the drug system, to seek authoritative outside analysis of how stakeholders would be affected. We do not know if the government has taken such steps, but **no independent impact analysis has been provided to the public**.

There has also been some apparent conflict between the content of the legislation and the statements of the Minister. For example, pharmacists have been told that not all professional allowances will be banned, and that some allowances that support training and education will be permitted. We have also heard that an allowance of up to 20% of the cost of a product will be permitted. This however, contradicts the very precise language of Bill 102, which prohibits a manufacturer from providing a “rebate” to pharmacies – and prohibits pharmacists from accepting “rebates” - where a “rebate” is defined as:

*“currency, a discount, refund, trip, free goods or any other prescribed benefit, but does not include a discount for prompt payment offered in the ordinary course of business”*

The result of the apparent conflict between the legislation and policy announcements has been to sow significant confusion among pharmacists. However, we believe that it is very clear that the government's true intentions should be contained and detailed in legislation – in law.

Finally, we do not believe that the government has allowed sufficient time for a thorough and proper consideration of this bill. The impression left by the rapid procedural steps to move Bill 102 through the legislative process is that this legislation is being rushed into law. Six weeks from tabling to the end of the committee phase has not provided sufficient time for affected stakeholders, including pharmacy, to complete detailed impact analyses and to fully consider the positive and negative aspects of the government's new plan. Given the scope of the plan, as well as the importance of the drug system to health care in Ontario, pharmacists feel that the process has been hasty, and has done a disservice to affected stakeholders.

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#### **Bill 102:**

Bill 102 is a broadly-enabling piece of legislation that would effect three basic, important changes to the organization and operation of Ontario's drug system.

It would create a new Executive Officer (EO) to oversee the system. As envisioned by the legislation, the EO would be outside both the legislature and the public service, and would have extremely broad powers.

The bill would prohibit the provision to pharmacies of professional allowances (called "rebates" in the bill) and the sale of a listed drug product for supply under the ODBA for a price that is higher than the drug benefit price listed in the Formulary.

And Bill 102 would lower the threshold for interchangeability of prescription medicines, permitting products that contain the same amounts of a drug with similar active ingredients and in a similar dosage form to be designated as interchangeable.

Other aspects of the Minister's plan to reform Ontario's drug system lie outside the bill, in the realm of regulation and policy.

#### **Analysis:**

The OCDA has several concerns and recommendations with respect to Bill 102. These apply to:

- The prohibition of professional allowances (called "rebates" in the bill)

- Pharmacists' discretion regarding interchangeable products (including pharmacist indemnification)
- Payment for professional services
- Pharmacy Council and Citizens' Council
- Alternative payments
- Premium dispensing fee
- Review of dispensing fee and mark-up
- Cost to operator
- Inspection powers and review and appeal
- Drafting revisions

**Professional Allowances:** By far the most serious impact on pharmacy of the legislation will be the elimination of professional allowances. The Minister, in public comments, has referred to these allowances as “nefarious”, and “cutting deals” for “back-door rebates”. We believe this reflects an important lack of understanding of the economics of pharmacy in Ontario.

Professional allowances are negotiated, in the free market, by pharmacies with generic drug manufacturers. Manufacturers compete with each other for the opportunity to supply interchangeable, multi-source medicines to pharmacies. The allowances agreed to between the parties represent a significant portion of the overall funding available to pharmacy to maintain and expand operations.

The reason professional allowances are so vital is that the sources of funding and reimbursement available to pharmacy from government are insufficient to cover operating costs. Pharmacists are not paid for services in the same manner as physicians or nurses. Compensation for pharmacy care comes primarily in the form of:

1. Dispensing fees. These fees have been kept artificially low by government, increasing only 2% since 1993, during which period the population of Ontario has increased by 13%, and inflation has equaled 27%.
2. Inventory allowances (or “mark-ups”). These have been limited to 10% of the cost of a medicine, and the new policy proposals would cap them at 8%. Given that drug wholesalers apply a 5.6% upcharge, this would leave pharmacists with a mere 2.4% inventory allowance.

Taken together, dispensing fees and inventory allowances do not currently cover the extensive costs associated with operating a pharmacy. In order to operate a pharmacy, pharmacists must:

- maintain the store itself
- purchase and stock medicines
- dispense prescriptions

- counsel patients
- coordinate patient care with physicians
- pay and train pharmacy staff
- continuously upgrade computer technology, and
- provide patient and community education programs

Once all of these costs are covered, pharmacists must account for their own pay and some degree of profit margin in their business, with whatever funds are left.

Since government reimbursement does not cover the cost of doing business, professional allowances have played a pivotal role in maintaining the continued economic viability of pharmacy in Ontario.

According to data provided by the OPA and our members, **the impact of prohibiting professional allowances will be to reduce overall funding to pharmacy by hundreds of millions of dollars per year.** Pharmacy cannot sustain this scale of funding cuts without significant impact on service and care to patients.

At a time when the province's population is aging and requiring ever higher levels of service and care, it is simply not viable to prohibit professional allowances, as Bill 102 would do, and expect pharmacies to maintain or enhance service to patients. Unless the government is prepared to develop an entirely new reimbursement model, and to create a new mechanism to compensate pharmacists, it is imperative that the legislation's provisions regarding professional allowances be amended. (See Appendix I – Proposed Amendments to Bill 102)

### **Pharmacists' Discretion – Interchangeable Products (including pharmacist indemnification):**

The language of Bill 102 is not clear, when it comes to the interchangeability of products. As a result, pharmacists attempting to follow the law with respect to when it is permissible to dispense a drug "in the same amounts of the same or similar active ingredients in the same or similar dosage form as the product prescribed" may face legal liability in doing so. Therefore, the OCDA recommends an amendment to the relevant section of the bill. (See Appendix I – Proposed Amendments to Bill 102)

### **Payment for Professional Services:**

Bill 102 proposes to give the Executive Officer the power to pay operators of pharmacies for professional services and to determine the amount of such payments. We have proposed amendments that would require that the EO negotiate and agree with a committee composed of two members of the OPA and two members of the OCDA regarding fees and conditions that must be met

for payments to be made. We have also recommended language to define “professional services” and to allow the definition to be expanded by regulation and/or through negotiation between the EO and the committee mentioned above. (See Appendix I – Proposed Amendments to Bill 102)

### **Pharmacy Council and Citizens’ Council:**

The Pharmacy and Citizens’ Councils are not currently established in the legislation. We call upon the committee to act on the Minister’s stated intent that they be in the legislation and the OCDA has provided proposed amendments to formally establish these bodies, set out their duties and provide for their composition, within Bill 102. (See Appendix I – Proposed Amendments to Bill 102)

### **Alternative Payments:**

To ensure fair and equitable treatment of pharmacists in the long-term care setting, we have proposed an amendment that would require that payments made to operators in this setting be no less than the amount provided for community pharmacists. (See Appendix I – Proposed Amendments to Bill 102)

### **Premium Dispensing Fee:**

The OCDA has proposed an amendment to provide the EO with the power to pay a premium dispensing fee, exceeding the usual dispensing fee, where “prescribed conditions” are met. This is designed to acknowledge a range of services that require a different reimbursement approach, including methadone maintenance therapy, intravenous infusion services, extemporaneous compounding and compliance packaging. (See Appendix I – Proposed Amendments to Bill 102)

### **Review of Dispensing Fee and Mark-Up**

Historically, dispensing fees have not kept pace with inflation, and inventory allowances have not taken into account the increasing use of expensive medicines. Therefore, we would request that the EO be required to review both dispensing fees and inventory allowances every three years, and that the recommended increase be no less than the increase in the Consumer Price Index. Accordingly, we have proposed amendments to the relevant sections of the bill (See Appendix I – Proposed Amendments to Bill 102)

### **Cost to Operator:**

Bill 102 makes the payment of the difference between the acquisition cost of a product and the drug benefit price subject to conditions to be prescribed by regulation. In order to remove uncertainty on this issue, we have recommended

amendments to ensure that the EO will pay the difference between cost of acquisition and drug benefit price, and will allow the pharmacist to claim the standard mark-up. In addition our proposed amendments would remove the provision that payment would be subject to conditions, since there is no indication of what those conditions would be. (See Appendix I – Proposed Amendments to Bill 102)

### **Inspection Powers and Review and Appeal:**

The audit powers provided to the EO and inspectors are overly broad in scope, and do not provide for review or appeal of an inspection or information requirement by the EO. Therefore, we have recommended amendments to the relevant sections of the bill. (See Appendix I – Proposed Amendments to Bill 102)

### **Powers of the Executive Officer:**

The new Executive Officer envisioned by the legislation would be vested with broad powers, the scope of which are unprecedented not only in Ontario, but in any jurisdiction in Canada. In addition, the EO would operate outside both the legislature and the public service. This raises certain questions with respect to transparency and public accountability and to concentration of authority in a single individual who is neither an elected official nor a public servant.

The OCDA has general concerns as to why this powerful position is to be created outside the existing structures of the Ministry of Health. In addition, we have certain specific concerns regarding the proposed operating guidelines of the EO, and have therefore proposed amendments to the relevant sections of the bill. (See Appendix I – Proposed Amendments to Bill 102)

### **Drafting Revisions:**

The OCDA recommends some technical amendments, to improve the drafting of the bill. (See Appendix I – Proposed Amendments to Bill 102)

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### **Policy Provisions:**

In addition to the provisions contained in Bill 102, the Minister has announced a number of policy proposals with the intent to reform Ontario's drug system. Among those that most significantly affect pharmacy are the following.

The Minister has proposed to establish a fund to begin compensating pharmacists for cognitive services through OHIP.

A Pharmacy Council would be created to increase pharmacist involvement in the ongoing development of pharmaceutical and health policy.

The dispensing fee for all drugs would increase from \$6.54 to \$7.00.

Inventory allowances, or “mark-ups”, are to be reduced from 10% to 8%, and capped at \$25.

Generic drug prices are to be reduced from 63% to 50% of the brand name equivalent.

**Analysis:**

The OCDA strongly supports some of these proposals, such as those that increase and better recognize pharmacists’ roles, but has serious concerns with respect to the limitations on current funding mechanisms, particularly in combination with the bill’s prohibition of professional allowances.

**Cognitive Services:**

The Minister’s announcement that the government intends to establish a fund to reimburse pharmacists for cognitive services is a welcome one. For the first time in Ontario, pharmacists have been recognized as key front-line providers of value-added services to patients and as key to the success of the health care system in Ontario.

We are eager to hear the details of this proposal, to understand which services will be included under this initiative, and to work with the Minister on the structure and implementation of his proposal.

**Pharmacy Council:**

We look forward to hearing more details regarding the proposed Pharmacy Council. We support the Minister’s stated intent that the Council would be established to identify support training mechanisms for medication management reviews as well as to address pharmacy policy going forward, including opportunities for pharmacists to work in primary care practices, such as Family Health Teams.

Given the importance of this initiative, the OCDA has recommended that the Pharmacy Council be established within the text of Bill 102. (See Appendix I – Proposed Amendments to Bill 102)

### **Dispensing Fee Increase:**

An increase in the dispensing fee is overdue, and has been long sought by Ontario pharmacists. However, the \$0.46 cent increase to \$7.00 is insufficient. Since 1993, the allowable dispensing fee has increased by only 2%, during a period in which inflation has increased by 27%. In real terms, this amounts to a cut of one-quarter in the reimbursement per prescription. During that period, costs to pharmacy have not remained static. Wages for pharmacists, technicians and other staff, technology costs and overall operating costs have increased significantly, as has the average cost of drugs per prescription.

The OCDA estimates that the true cost of dispensing a prescription is between \$10 and \$12, meaning that pharmacies now lose money for each prescription dispensed under the ODBA. Therefore, we would recommend that the government revisit the proposed fee of \$7.00, and apply a more appropriate increase.

### **Inventory Allowances:**

The Minister's proposal to cut inventory allowances ("mark-ups") from 10% to 8%, and to cap claims at \$25 is not economically viable. First, the government should be aware that drug wholesalers apply an upcharge of 5.6% to each product, before it reaches pharmacy shelves. This leaves a paltry percentage inventory allowance for pharmacists – one that does not cover the cost of acquiring and stocking medicines. The \$25 cap is particularly vexing, given that trends among new drugs show that many are extremely expensive, such as biotechnology drugs and medicines used to treat conditions such as cancer, HIV/AIDS, rheumatoid arthritis, multiple sclerosis and Crohn's disease.

The cut and cap on inventory allowances will create a disincentive for pharmacists to stock many new drugs. Pharmacies will actually lose money by doing so. If this proposal is not changed, many pharmacists have stated that they will not be able to stock medicines that exceed \$312 per claim. This would represent a major negative impact for patients.

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### **Conclusion:**

**The combination of Bill 102 and the Minister of Health's policy announcements would have a devastating effect on community pharmacy in Ontario.**

While there are positive aspects to the proposals, they are greatly outweighed by the negative impact the broad and deep funding cuts would have on the practice and the economics of pharmacy. The OCDA believes that the drafting of the bill

and its attendant policy proposals reflect a lack of understanding of the economic reality of operating pharmacy. **It is simply not possible to cut hundreds of millions of dollars per year from pharmacy funding, and yet expect pharmacists to continue to maintain or increase levels of pharmacy service and care.**

If Bill 102 and the associated policy provisions are not amended, the effect on pharmacy will be severe. **Ontarians may expect pharmacy closures, reduced store opening hours, pharmacist and staff layoffs, increased waiting times at dispensaries, reduced access to expensive new medicines, and reduced patient and community education programs.**

Ontario's population is growing and aging. In simple terms, that means more sick people, needing more prescription drugs. It also means a greater need for pharmacists to provide extended and enhanced care, including preventative and health management care, to patients. Bill 102 and the announced policies are not consistent with that growing need.

It is imperative that the government's plan to reform Ontario's drug system be significantly amended, in close, good-faith consultation and negotiation with pharmacists.

## Appendix I Proposed Amendments to Bill 102

### Bill 102 2006

#### An Act to amend the Drug Interchangeability and Dispensing Fee Act and the Ontario Drug Benefit Act

Her Majesty, by and with the advice and consent of the Legislative Assembly of the Province of Ontario, enacts as follows:

#### PART I AMENDMENTS TO THE DRUG INTERCHANGEABILITY AND DISPENSING FEE ACT

**1. (1) The definition of "designated" in section 1 of the *Drug Interchangeability and Dispensing Fee Act* is repealed and the following substituted:**

"designated" means designated by the executive officer in the Formulary; ("désigné")

**(2) Section 1 of the Act is amended by adding the following definitions:**

"executive officer" means the executive officer of the Ontario public drug programs appointed under the *Ontario Drug Benefit Act*; ("administrateur")

"Formulary" means the Formulary that the executive officer is required to keep, maintain and publish under the *Ontario Drug Benefit Act*; ("Formulaire des médicaments" "medicaments")

**2. The Act is amended by adding the following section:**

#### **Executive officer and interchangeability**

**1.1 (1)** The executive officer may designate a product as being interchangeable with another product by designating it as such in the Formulary.

#### **Formulary and interchangeability**

(2) A product becomes interchangeable with another product on the effective date of its being designated as interchangeable with that product, and ceases to be interchangeable with that product on the effective date of the removal of its interchangeability designation by the executive officer.

#### **Requirements for interchangeability**

(3) The executive officer may designate a product as being interchangeable with another product if it is in the public interest to do so, but shall not do so if,  
(a) it does not contain a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the other product; or

(b) the prescribed conditions under clause 14 (1) (a) have not been met.

### **Ceasing to be interchangeable**

(4) The executive officer may remove a product's interchangeability designation,

(a) where authorized to do so under subsection 12.1 (7);

(b) if one of the conditions prescribed under clause 14 (1) (b) has been breached; or

(c) in any case, if he or she considers it advisable in the public interest to do so.

### **Modification**

(5) Any modification of a designation takes place on the effective date of its being designated in the Formulary as a modification.

### **Transitional**

(6) A product that was interchangeable with another product immediately before October 1, 2006 continues to be interchangeable with that product until its interchangeability designation is removed by the executive officer.

### **3. Subsection 4 (5) of the Act is repealed and the following substituted:**

#### **Selection of interchangeable product**

~~(5) If a prescription directs the dispensing of a product that is not an interchangeable product and there is an interchangeable product that contains a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the product prescribed, the dispenser may dispense the interchangeable product.~~

### **4. The Act is amended by adding the following sections:**

#### **~~Rebate, etc.~~**

#### **Rebates**

**12.1 (1)** A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any interchangeable product; or

(b) for any product in respect of which the manufacturer has made an application to the executive officer for designation as an interchangeable product, while that application is being considered.

#### **May not accept rebate**

(2) No person shall accept a rebate that is mentioned in subsection (1), either directly or

indirectly.

### **Professional allowance**

(2.1) Subject to subsection (2.2), a manufacturer may provide a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies.

### **Disclosure of professional allowance**

(2.2) A manufacturer that provides a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies shall inform the executive officer of the details of the professional allowance.

### **Executive officer may make order**

(3) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (4).

### **Calculation**

(4) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (3):

1. The amount shall be calculated by determining the difference between the expected value of all units of the drug products purchased and the actual cost of acquiring those units by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.
2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the products.
3. The actual cost of acquiring those products mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for all the products by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

### **Reconsideration**

(5) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (4) is not correct, and the executive officer shall reconsider the order based on that evidence.

### **Actions of executive officer after reconsideration**

(6) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision:

1. Affirm the order.
2. Rescind the order.
3. Vary the order.

#### **Executive officer may act**

(7) Where a manufacturer has not complied with an order under subsection (3) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (5) and the order has been affirmed or varied under subsection (6) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (3) requiring the manufacturer to pay a revised amount calculated under subsection (4), or do either or both of the following:

1. If the drug that is the subject of the order is an interchangeable product, remove its designation.
2. Not make further designations of any of the manufacturer's products as interchangeable under this Act, or as listed drug products under section 1.3 of the *Ontario Drug Benefit Act*, nor consider any of its products for approval under section 16 of that Act, until such time as the executive officer is of the opinion that the manufacturer is no longer offering the rebate.

#### **Limit on reconsideration**

(8) Subsections (5) and (6) do not apply to a further order mentioned in subsection (7).

#### **Required notice**

(9) Where the executive officer proposes to act under paragraph 2 of subsection (7), the executive officer shall serve the manufacturer with at least 30 days notice.

#### **Definitions**

(10) In this section,

~~"drug benefit price"~~ means, with respect to a product,

(a) its drug benefit price under the *Ontario Drug Benefit Act*,

(b) in the case of a product that is not a benefit under the *Ontario Drug Benefit Act*, a price submitted by the manufacturer under the regulations that has been posted by the executive officer in the Formulary, or

(c) in the case of a product mentioned in clause (1) (b), the price submitted by the manufacturer; (~~"prix au titre du régime de médicaments"~~ "medicaments")

"professional allowance" means a benefit in the form of money that is provided by a manufacturer in the ordinary course of business to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies. ("allocations professionnelles")

~~"rebate", subject to the regulations,"~~ includes, ~~without being limited to, currency,~~ a discount, refund, trip, free goods or ~~any~~ other prescribed benefit, but does not include a [professional allowance or a](#) discount for prompt payment offered in the ordinary course of business. ("rabais")

## **Regulations**

(11) The Lieutenant Governor in Council may make regulations clarifying the definition of ~~"rebate"~~ in this section, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition and clarifying how the calculations are to be made in this section.

## **Rules re s. 12.1**

**12.2** (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 12.1:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.
2. An order must set out how any amount required to be paid under the order was calculated, specify any right of reconsideration that is available, and the time within which reconsideration is available.
3. The order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with a person at any place of business of the manufacturer who appears to be in control or management of the place of business.
4. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was made, if the previous order has not been complied with.
5. An order must set out the time period in which the manufacturer is required to comply with the order.
6. An order must specify the consequences for failing to comply with the order.

## **Same, publication of enforcement action**

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers against whom the executive officer has taken action under section 12.1 and may also publish any information he or she considers appropriate about the action that has been taken.

## **No appeal**

(3) There is no appeal from a decision or action of the executive officer under section 12.1, except as provided for in that section.

## **Non-application of SPPA**

(4) The *Statutory Powers Procedure Act* does not apply to anything done by the executive officer

under section 12.1.

**5. (1) Subsection 14 (1) of the Act is amended by adding the following clause:**

(d) defining any word or expression used in this Act but not defined in this Act.

**(2) Clause 14 (2) (a) of the Act is repealed and the following substituted:**

(a) it does not contain a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the other product; or

**(3) Subsections 14 (2), (3), (4) and (5) of the Act are repealed.**

**(4) Section 14 of the Act is amended by adding the following subsection:**

**Retroactive**

(g) A regulation is, if it so provides, effective with reference to a period before it is filed.

**PART II  
AMENDMENTS TO THE  
*Ontario Drug Benefit Act***

**6. The *Ontario Drug Benefit Act* is amended by adding the following section:**

**Principles**

**0.1** In this Act, the following principles are recognized:

1. The public drug system aims to meet the needs of Ontarians, as consumers and taxpayers.
2. The public drug system aims to involve consumers and patients in a meaningful way.
3. The public drug system aims to operate transparently to the extent possible for all persons with an interest in the system, including, without being limited to, patients, health care practitioners, consumers, manufacturers, wholesalers and pharmacies.
4. The public drug system aims to consistently achieve value-for-money and ensure the best use of resources at every level of the system.
5. Funding decisions for drugs are to be made on the best clinical and economic evidence available, and will be openly communicated, to the extent possible.

[6. The Minister has an obligation to ensure that eligible persons have uniformly timely access, at the point of dispensing, to listed drug products and interchangeable products.](#)

**7. (1) The definition of "designated" in section 1 of the *Act* is repealed and the**

**following substituted:**

"designated" means designated in the Formulary by the executive officer; ("désigné")

**(2) Section 1 of the Act is amended by adding the following definitions:**

"Appeal Board" means the Health Services Appeal and Review Board under the Ministry of Health Appeal and Review Boards Act, 1998 ("Commission d'appel")

"executive officer" means the executive officer of the Ontario public drug programs appointed under section 1.1; ("administrateur")

"designated pharmaceutical product" means a product prescribed as a designated pharmaceutical Product

"extemporaneous preparation" means a drug or combination of drugs prepared or compounded in a pharmacy according to a prescription

"Formulary" means the Formulary that the executive officer is required to keep, maintain and publish under section 1.2; ("Formulaire des médicaments")

"professional services" means any of the following services provided by a member of the Ontario College of Pharmacists to a patient:

(a) methadone dispensing and maintenance therapy;

(b) intravenous infusion services;

(c) specialty compounding;

(d) compliance packaging;

(e) needle and syringe exchange programs;

(f) any additional services that are prescribed; and

(g) any additional services that are agreed to by the executive officer and the committee referred to in clause 1.1 (2) (j).

**(3) The definition of "Minister" in section 1 of the Act is repealed and the following substituted:**

"Minister" means the Minister of Health and Long-Term Care or any other member of the Executive Council to whom the administration of this Act is assigned under the *Executive Council Act*; ("ministre")

**(4) Section 1 of the Act is amended by adding the following definition:**

"prescribed" means prescribed in the regulations; ("prescrit")

## 8. The Act is amended by adding the following sections:

### Executive officer

1.1 (1) The Lieutenant Governor in Council shall appoint an executive officer for the Ontario public drug programs.

### Functions and powers

(2) Subject to this Act and the regulations, it is the function of the executive officer, and he or she has the power, to perform any functions or duties that he or she may have under this Act and the regulations, under the *Drug Interchangeability and Dispensing Fee Act* and its regulations and under any other Act or regulation, and without in any way restricting the generality of the foregoing,

(a) to administer the Ontario public drug programs;

(b) to keep, maintain and publish the Formulary;

(c) to make this Act apply in respect of the supplying of drugs that are not listed drug products as provided for in section 16;

(d) to designate products as listed drug products, listed substances and designated pharmaceutical products for the purposes of this Act, and to remove or modify those designations;

(e) to designate products as interchangeable with other products under the *Drug Interchangeability and Dispensing Fee Act*, and to remove or modify those designations;

(f) to negotiate agreements with manufacturers of drug products, agree with manufacturers as to the drug benefit price of listed drug products, negotiate drug benefit prices for listed substances with suppliers, and set drug benefit prices for designated pharmaceutical products;

(g) to require any information that may or must be provided to the executive officer under this Act or the regulations or any other Act or regulation to be in a format that is satisfactory to the executive officer;

(h) to make payments under the Ontario public drug programs;

(i) to establish clinical criteria under section 23; and

(j) to ~~pay~~negotiate and agree on the payments to be made to operators of pharmacies for professional services, ~~and to determine the amount of such payments subject to the prescribed conditions, if any,~~ with a committee comprised of two members of the Ontario Pharmacists' Association and two members of the Ontario Chain Drug Association, and to pay operators of pharmacies for such professional services.

### Regulations

- (3) The Lieutenant Governor in Council may make regulations,
- (a) clarifying, modifying or restricting the functions and powers of the executive officer;
  - (b) providing for additional functions and powers of the executive officer.

### **Formulary**

**1.2** (1) The executive officer shall keep, maintain and publish a Formulary.

### **Contents**

- (2) The Formulary shall set out,
- (a) the listed drug products and listed substances for the purposes of this Act;
  - (b) the drug benefit price for listed drug products, listed substances and designated pharmaceutical products;
  - (c) the products that are designated as interchangeable for the purposes of the *Drug Interchangeability and Dispensing Fee Act*; and
  - (d) any other information required under this or any other Act.

### **Other information**

(3) In addition to anything mentioned in subsection (2), the Formulary may set out any other information or material the executive officer considers necessary or advisable.

### **Publication**

(4) The executive officer shall publish the Formulary on the website of the Ministry and may publish it in any other format the executive officer considers advisable.

### **Where conflict**

(5) In the event of a conflict between what is posted on the Ministry's website under subsection (4) and what is posted in another format, the Ministry's website prevails.

### **Listing**

**1.3** (1) A drug product becomes a listed drug product on the effective date of its being designated in the Formulary as a listed drug product, and ceases to be a listed drug product on the effective date of that designation being removed.

### **Requirements for listing**

(2) The executive officer may designate a drug product in the Formulary as a listed drug product where the executive officer considers it to be in the public interest to do so, but shall not do so if

the prescribed conditions under clause 18 (1) (b) have not been met.

### **Modification**

(3) Any modification of a designation takes place on the effective date of its being designated in the Formulary as a modification.

### **Transitional**

(4) A drug product that was a listed drug product immediately before October 1, 2006 continues to be a listed drug product until it is removed from the Formulary as a listed drug product under this section.

### **Pharmacy Council**

1.4 (1) The Minister shall establish a Pharmacy Council whose duties shall be to provide expert advice to the Minister, to ensure the involvement of pharmacists in the development of pharmaceutical and health policy including in the development of reimbursement models for pharmacists, and to identify support and training mechanisms for medication management reviews.

(2) Subject to subsection (4), the Pharmacy Council shall be composed of one representative nominated by each of the following: the Minister, the Ontario Pharmacists' Association, the Ontario College of Pharmacists, the Ontario Chain Drug Association, the Canadian Society of Hospital Pharmacists- Ontario Branch, the Faculty of Pharmacy at the University of Toronto, the Ontario Medical Association and the Citizens' Council.

(3) The Pharmacy Council shall be chaired jointly by the representatives of the Minister and the Ontario Pharmacists' Association.

(4) The chairs may jointly agree to expand the composition of the Pharmacy Council by inviting another organization or organizations with an interest in pharmacy or pharmaceutical and health policy to nominate a representative.

### **Citizens' Council**

1.5 (1) The Minister shall establish a Citizens' Council whose duty shall be to ensure the involvement of patients in the development of pharmaceutical and health policy.

(2) The Citizens' Council shall be composed of <\*> members nominated by <\*> and <\*> members nominated by <\*>.

**9. Subsection 2 (1) of the Act is amended by striking out "designated" and substituting "prescribed".**

**10. (1) Subsection 4 (1) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(2) Subsection 4 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(3) Subsection 4 (3) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(4) Subsection 4 (4) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(5) Paragraph 4 of subsection 4 (5) of the Act is repealed and the following substituted:**

4. Subject to the prescribed conditions, if any, if the acquisition cost, for the operator of the pharmacy, of the drug product dispensed is greater than the ~~sum of the~~ drug benefit price for that product ~~and the mark-up referred to in paragraph 3 of subsection 6 (1)~~, determine the amount by which they differ.

**11. (1) Subsections 5 (1) and (2) of the Act are repealed and the following substituted:**

#### **Payment of claim of operator**

(1) Subject to subsection (2), an operator of a pharmacy who submits to the executive officer a claim for payment in respect of supplying a listed drug product for an eligible person pursuant to a prescription is entitled to be paid by the executive officer the amount provided for under section 6.

#### **Alternative payments**

(2) The executive officer may pay the operator of a pharmacy an amount different from the amount provided for under section 6 in respect of a claim or claims under subsection (1) for prescribed classes of eligible persons, subject to any prescribed requirements. [Payment pursuant to this subsection shall not be less than the amount provided for under section 6.](#)

#### **Transitional**

(2.1) Any agreement that was in place under subsection (2), as it existed before October 1, 2006, that was in effect immediately before that date continues in force, with the executive officer substituted for the Minister, until it is terminated under its terms.

**(2) Subsection 5 (3) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**12. (1) Subsection 6 (1) of the Act is repealed and the following substituted:**

#### **Amount executive officer to pay**

(1) The amount the executive officer shall pay under subsection 5 (1) in respect of a listed drug product is the amount calculated by adding the amounts determined under paragraphs 1, 2 and 3 and subtracting from that total the maximum co-payment that may be charged in respect of the supplying of a listed drug product for an eligible person, as provided for in the regulations:

1. The dispensing fee determined under subsection (2).

2. The drug benefit price for the drug product, but, if there are other listed drug products that are interchangeable with the drug product, the drug benefit price shall be deemed to be the lowest of the drug benefit prices for the drug product and the listed drug products that are interchangeable with it.

3. The prescribed mark-up on that price.

**(2) Subsection 6 (2) of the Act is amended by striking out "the Minister" in the portion before clause (a) and substituting "the executive officer".**

**(3) Clause 6 (2) (a) of the Act is repealed.**

**(3.1) Clause 6(2)(c) of the Act is amended by adding "Subject to section 6(2.1)" before "in all other cases".**

**(3.2) Section 6 of the Act is amended by adding the following subsections:**

**Premium Dispensing Fee**

**(2.1) The executive officer may pay the operator of a pharmacy a dispensing fee that exceeds the prescribed dispensing fee where the prescribed conditions have been met.**

**Review of Dispensing Fee and Mark-up**

**(2.2) Not more than three years after the coming into force of this Act, and not more than every three years thereafter, the executive officer shall review the prescribed dispensing fee and the prescribed mark-up and shall recommend to the Lieutenant Governor in Council that they be increased by a percentage that is not less than the percentage increase in the cost of living since the previous review, as measured by the Consumer Price Index in Ontario.**

**(4) Subsection 6 (3) of the Act is repealed and the following substituted:**

**Same, high acquisition cost**

(3) Subject to the prescribed conditions, if any, if the acquisition cost of a listed drug product for an operator of a pharmacy is greater than the ~~sum of the~~ drug benefit price for the drug product determined under paragraph 2 ~~of subsection (1) and the mark-up on that price, referred to in paragraph 3~~ of subsection (1), the executive officer shall also pay, under subsection 5 (1), the difference between the acquisition cost for the drug product and that sum.

**(5) Subsection 6 (5) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(6) The Act is amended by adding the following section:**

**6.1 An operator of a pharmacy who submits to the executive officer a claim for payment in respect of professional services is entitled to be paid by the executive officer, for such professional services, the amount that the executive officer has negotiated and agreed to with the committee referred to in clause 1.1 (2) (j).**

**13. Section 8 of the Act is repealed.**

**14. (1) Subsection 9 (1) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**(2) Subsection 9 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(3) Section 9 of the Act is amended by adding the following subsection:  
Transitional**

**(4) Any agreement under subsection (1) that was in effect immediately before October 1, 2006 continues in force, with the executive officer substituted for the Minister, until it is terminated under its terms.**

**15. (1) Subsection 11 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**(2) Subsection 11 (2) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**16. (1) Subsection 11.1 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**(2) Subsection 11.1 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(3) Subsection 11.1 (3) of the Act is amended by striking out "the Minister" and substituting "the executive officer",**

**(a) in the portion before clause (a); and**

**(b) in clause (a).**

**(4) Subsection 11.1 (6) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**(5) Subsection 11.1 (7) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**17. (1) Subsection 11.2 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**(2) Subsection 11.2 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(3) Subsection 11.2 (3) of the Act is amended by striking out "the Minister" and substituting "the executive officer",**

**(a) in the portion before clause (a); and**

**(b) in clause (a).**

**(4) Subsection 11.2 (5) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**(5) Subsection 11.2 (6) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**18. Subsection 11.3 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**19. The Act is amended by adding the following sections:**

**Supply to be at drug benefit price**

**11.4 (1)** A manufacturer shall not sell a listed drug product, for the purpose of supplying a drug product under this Act, for a price that is higher than its drug benefit price as listed in the Formulary.

**Agreement not to exceed drug benefit price**

(2) A manufacturer, in agreeing to a drug benefit price with the executive officer under section 22, shall agree to comply with subsection (1).

**Executive officer may make order**

(3) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (4).

**How amount calculated**

(4) The amount that the manufacturer is required to pay under subsection (3) is the amount determined by the formula:

$$A = Q (P - DBP)$$

where,

"A" is the amount to be paid by the manufacturer,

"P" is the price for which the manufacturer is selling the listed drug product,

"DBP" is the drug benefit price, and

"Q" is the number of units of the listed drug product sold at the higher price.

## **Reconsideration**

(5) Within 14 days of being served with an order under subsection (3), the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (4) is not correct, and the executive officer shall reconsider the order based on that evidence.

## **Actions of executive officer after reconsideration**

(6) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision.

1. Affirm the order.
2. Rescind the order.
2. Vary the order.
- 3.

## **Executive officer may act**

(7) Where a manufacturer has not complied with an order under subsection (3) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (5) and the order has been affirmed or varied under subsection (6) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (3) requiring the manufacturer to pay a revised amount calculated under subsection (4), or do either or both of the following:

1. Remove the designation of the drug that is the subject of the order as a listed drug product.
2. Not make further designations of any of the manufacturer's drug products as listed drug products under section 1.3, nor consider any of its drug products for approval under section 16, nor designate any of its products as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* until such time as the executive officer is of the opinion that the manufacturer is selling the drug product for the drug benefit price.

## **Limit on reconsideration**

(8) Subsections (5) and (6) do not apply to a further order mentioned in subsection (7).

## **Required notice**

(9) Where the executive officer proposes to act under paragraph 2 of subsection (7), the executive officer shall serve the manufacturer with at least 30 days notice.

## **Rebates, etc.**

**11.5** (1) A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any listed drug product or listed substance; or

(b) for any drug in respect of which the manufacturer has made an application to the executive officer for designation as a listed drug product, while that application is being considered.

### **May not accept rebate**

(2) No person shall accept a rebate that is mentioned in subsection (1), either directly or indirectly.

### **Professional allowance**

(2.1) Subject to subsection (2.2), a manufacturer may provide a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies.

### **Disclosure of professional allowance**

(2.2) A manufacturer that provides a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies shall inform the executive officer of the details of the professional allowance.

### **Executive officer may make order**

(3) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (4).

### **Calculation**

(4) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (3):

1. The amount shall be calculated by determining the difference between the expected value of all units of drug products and listed substances purchased and the actual cost of acquiring those units by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the listed drug products and listed substances.

3. The actual cost of acquiring those products and substances mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for the drug products and listed substances by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

### **Deemed drug benefit price**

(5) For the purposes of subsection (4), the drug benefit price of a drug in respect of which clause (1) (b) applies shall be deemed to be the price submitted by the manufacturer.

## Reconsideration

(6) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (4) is not correct, and the executive officer shall reconsider the order based on that evidence.

## Actions of executive officer after reconsideration

(7) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision.

1. Affirm the order.
2. Rescind the order.
3. Vary the order.

## Executive officer may act

(8) Where a manufacturer has not complied with an order under subsection (3) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (6) and the order has been affirmed or varied under subsection (7) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (3) or do either or both of the following:

1. If the drug that is the subject of the order is a listed drug product, remove its designation.
2. Not make further designations of any of the manufacturer's ~~drug~~ products as listed drug products under section 1.3, nor consider any of its ~~drug~~ products for approval under section 16, nor designate any of its products as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* until such time as the executive officer is of the opinion that ~~the~~ manufacturer is no longer offering the rebate.

## Limit on reconsideration

(9) Subsections (6) and (7) do not apply to a further order mentioned in subsection (8).

## Required notice

(10) Where the executive officer proposes to act under paragraph 2 of subsection (8), the executive officer shall serve the manufacturer with at least 30 days notice.

## Definition

(11) In this section,

[“professional allowance” means a benefit in the form of money that is provided by a manufacturer in the ordinary course of business to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies. \(“allocations professionnelles”\)](#)

~~"rebate", subject to the regulations,"~~ includes, ~~without being limited to, currency,~~ a discount, refund, trip, free goods or ~~any~~ other prescribed benefit, but does not include a [professional allowance or a](#) discount for prompt payment offered in the ordinary course of business. (["rabais"](#))

### **Rules re ss. 11.4 and 11.5**

**11.6** (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 11.4 or 11.5:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.
2. An order must set out how any amount required to be paid under the order was calculated, and specify any right of reconsideration that is available and the time within which the reconsideration is available.
3. The order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with a person at any place of business of the manufacturer who appears to be in control or management of the place of business.
4. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was made, if the previous order has not been complied with.
5. An order must set out the time period in which the manufacturer is required to comply with the order.
6. An order must specify the consequences for failing to comply with the order.

### **Same, publication of enforcement action**

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers against whom the executive officer has taken action under section 11.4 or 11.5 and may also publish any information he or she considers appropriate about the action that has been taken.

### **No appeal**

(3) There is no appeal from a decision or action of the executive officer under section 11.4 or 11.5, except as provided for in those sections.

### **Non-application of SPPA**

(4) The *Statutory Powers Procedure Act* does not apply to anything done by the executive officer under sections 11.4 and 11.5.

## **20. Section 12 of the Act is repealed and the following substituted:**

### **Minister and executive officer to consult**

**12.** The Minister and the executive officer may consult with persons or organizations representing eligible persons, manufacturers, operators of pharmacies, physicians, suppliers of

listed substances, wholesalers and companies that own, operate or franchise pharmacies with respect to the amounts payable under this Act and other matters of mutual concern arising out of this Act and the regulations, and the *Drug Interchangeability and Dispensing Fee Act* and its regulations.

**21. (1) Subsection 13 (1) of the Act is amended by adding "and the executive officer" after "The Minister" at the beginning.**

**(2) Subsection 13 (2) of the Act is amended by adding "and the executive officer" after "The Minister" at the beginning.**

**(3) Subsection 13 (3) of the Act is repealed and the following substituted:  
Disclosure**

(3) The Minister and the executive officer shall disclose personal information if all prescribed conditions have been met and the disclosure is necessary for purposes related to the administration of this Act or for such other purposes as may be prescribed, but shall not disclose the information if, in his or her opinion, the disclosure is not necessary for those purposes.

**(4) Subsection 13 (4) of the Act is amended by adding "and the executive officer" after "the Minister".**

**22. The Act is amended by adding the following section:**

#### **Requirement to provide information**

**13.1** (1) For the purposes of determining compliance with this Act or the regulations or with the *Drug Interchangeability and Dispensing Fee Act* and its regulations, the executive officer may require a manufacturer, wholesaler, supplier of a listed substance, operator of a pharmacy or a company that owns, operates or franchises pharmacies to provide information other than personal information to the executive officer, either in response to a specific request, or at regular intervals.

#### **Time and form**

(2) The executive officer may specify the time at which and the form in which the information must be provided.

#### **Publication**

(3) Where the executive officer requires that information be provided at regular intervals, the executive officer shall publish the manner and form that are required on the website of the Ministry, and may publish them in any other format that he or she considers appropriate.

#### **Compliance required**

(4) ~~The~~ [Subject to subsection 14.1 \(1\), the](#) manufacturer, wholesaler, supplier of listed substances, operator of a pharmacy or company that owns, operates or franchises pharmacies shall comply with every requirement to provide information under this section.

## Where conflict

(5) In the event of a conflict between what is posted on the Ministry's website under subsection (3) and what is posted in another format, the Ministry's website prevails.

**23. Subsections 14 (2), (3), (4) and (5) of the Act are repealed and the following substituted:**

### Examine books

(2) Subject to subsection (5), an inspector may examine records relating to a claim for payment under this Act, in whatever form, in the possession or under the control of an operator of a pharmacy or a physician, if the inspector believes on reasonable grounds that the records will assist the inspector in determining the accuracy and completeness of a claim for payment of the operator or physician or of information they are required to submit under this Act or the regulations, or in determining whether they have complied with this Act and the regulations.

### Same

~~(3) An~~ Subject to subsection (5), an inspector may examine records relating to a claim for payment under this Act, in whatever form, in the possession or under the control of a wholesaler, manufacturer, supplier of a listed substance, operator of a pharmacy or a company that owns, operates or franchises pharmacies, if the inspector believes on reasonable grounds that the records will assist the inspector in determining the accuracy and completeness of a claim for payment of an operator of a pharmacy or physician or in determining whether the wholesaler or manufacturer has complied with this Act and the regulations.

### Copies

(4) In carrying out an inspection under this section, the inspector may, upon giving a receipt for it, take away a record, including a sales or a marketing record, for the purpose of making a copy, but the copy shall be made and the record shall be returned as promptly as reasonably possible.

### Notice

(5) The inspector shall not carry out an inspection under this section unless the inspector has given the operator of a pharmacy, physician, wholesaler, manufacturer, supplier of a listed substance, or company that owns, operates or franchises pharmacies, as the case may be, seventy-two hours notice in writing of the inspector's intention to carry out an inspection under this section.

**23.1 The Act is amended by adding the following section:**

### Review to Appeal Board and Stay

14.1 (1) Any person who is affected by a requirement to provide information under section 13.1 or who is subject to an inspection under section 14 may request a review of the requirement under section 13.1 or of the decision to conduct an inspection or the conduct of the inspection, as the case may be, from the Appeal Board. A request for review under this section stays the obligation to comply under subsection 13 (4) or the inspection, as the case may be, until the disposition of

[the review.](#)

### **Powers of Appeal Board**

[\(2\) After conducting a review, the Appeal Board may,](#)

[\(a\) confirm the requirement under section 13.1 or the decision to conduct an inspection under section 14 and make such order as it considers proper in regard to the scope of the requirement or the conduct of the inspection, as the case may be; or](#)

[\(b\) relieve the applicant from the requirement under section 13.1 or order that there be no inspection under section 14.](#)

### **Appeal to Divisional Court**

[\(3\) Any party to the proceedings before the Appeal Board under this Act may appeal from its decision or order to the Divisional Court in accordance with the rules of court.](#)

### **Powers of court on appeal**

[\(4\) An appeal under this section may be made on questions of law or fact or both and the court may affirm or may rescind the decision of the Appeal Board and may exercise all powers of the Appeal Board under this section and as the court considers proper and for such purposes the court may substitute its opinion for that of the Appeal Board, or the court may refer the matter back to the Appeal Board for review, in whole or in part, in accordance with such directions as the court considers proper.](#)

### **24. (1) Clause 15 (1) (b) of the Act is repealed and the following substituted:**

(b) submits to the executive officer a claim for payment where the executive officer is not required to make any payment or where the claim is in excess of the amount the executive officer is required to pay;

**(2) Clause 15 (1) (e) of the Act is amended by adding "or the *Drug Interchangeability and Dispensing Fee Act*" after "administration of this Act".**

**(3) Subsection 15 (5) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(4) Subsection 15 (6) of the Act is repealed and the following substituted:**

**Same**

(6) The minimum penalty for each offence under clause (1) (b) is two times the difference between the amount for which a claim was submitted to the executive officer and the amount the executive officer is required to pay.

### **25. Section 16 of the Act is repealed and the following substituted:**

#### **Unlisted drugs, special case**

**16. (1) If a physician informs the executive officer that the proper treatment of a patient who is**

an eligible person requires the administration of a drug for which there is not a listed drug product, the executive officer may make this Act apply in respect of the supplying of that drug as if it were a listed drug product by so notifying the physician.

#### **Same**

(2) The drug benefit price of a drug referred to in subsection (1) shall be the amount determined by the executive officer in accordance with the regulations.

#### **Listed drugs, special case**

(3) If a physician informs the executive officer that the proper treatment of a patient who is an eligible person requires the administration of a drug for which there are one or more listed drug products but for which the conditions for payment under section 23 are not satisfied, the executive officer may make this Act apply in respect of the supplying of those listed drug products as if the conditions were satisfied.

#### **Notice to operator**

(4) An operator of a pharmacy is not liable for contravening this Act or the regulations in respect of supplying a drug referred to in subsection (1) or a listed drug product referred to in subsection (3) unless the operator has received notice from the physician or from the executive officer that [the executive officer has made this Act ~~applies to that supplying~~ apply in respect of the supplying of a drug referred to in subsection \(1\) or a listed drug product referred to in subsection \(3\).](#)

#### **Retroactivity**

(5) Where the executive officer may make this Act apply in respect of the supplying of a drug or a listed drug product under this section, the executive officer may make that application retroactive to a date determined by the executive officer.

### **26. Subsections 17 (2) and (3) of the Act are repealed and the following substituted:**

#### **Determination of drug benefit price**

(2) The executive officer has the authority to,

(a) determine the conditions which must be met before a pharmaceutical product, including an extemporaneous preparation, is designated as a designated pharmaceutical product; and

(b) determine the drug benefit price of a designated pharmaceutical product, including determining a formula by which the drug benefit price may be calculated.

#### **Section 22 does not apply**

(3) Section 22 does not apply for the purposes of this section.

#### **Publication**

(4) The executive officer shall publish, on the Ministry's website and in any other format the executive officer considers appropriate, any conditions or formulas that the executive officer

determines under subsection (2).

#### **Where conflict**

(5) In the event of a conflict between what is posted on the Ministry's website under subsection (4) and what is posted in another format, the Ministry's website prevails.

#### **27. (1) Subsection 18 (1) of the Act is amended by adding the following clauses:**

(O.a) defining any word or expression used in this Act but not defined in this Act;

(O.a.1) ~~governing~~[prescribing additional services as](#) professional services for the purposes of clause 1.1 (2) (j); ~~including defining "professional services", governing payments that may be made for professional services, including governing to whom payments may be made, and prescribing conditions to which the executive officer is subject in making payments for professional services;~~ [and section 6.1;](#)

**(2) Clause 18 (1) (a) of the Act is amended by striking out "designating" and substituting "prescribing".**

**(3) Clauses 18 (1) (c) and (d) of the Act are repealed.**

**(4) Clause 18 (1) (e.1) of the Act is repealed and the following substituted:**

(e.1) prescribing the manner of determining acquisition costs of drug products, for the purposes of subsections 4 (5), 6 (3) and 6 (4), and prescribing conditions for the purposes of paragraph 4 of subsection 4 (5) and for the purposes of subsection 6 (3);

**(5) Subsection 18 (1) of the Act is amended by adding the following clause:**

(e.1.2) prescribing classes of eligible persons and setting out requirements for the purposes of subsection 5 (2);

**(6) Clause 18 (1) (e.2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(7) Clause 18 (1) (e.3) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(8) Clause 18 (1) (g) of the Act is repealed.**

**(9) Clause 18 (1) (g.1) of the Act is repealed and the following substituted:**

(g.1) prescribing the mark-up of the drug benefit price the executive officer will pay under subsection 6 (1);

**(10) Clause 18 (1) (g.3) of the Act is repealed.**

**(11) Clause 18 (1) (g.4) of the Act is repealed and the following substituted:**

(g.4) prescribing the dispensing fee ~~and~~ [for the purposes of subclause 6 \(2\) \(c\) \(i\) and the conditions for the payment of the dispensing fee for the purposes of ~~subclause 6 \(2\) \(e\)~~ \[subsubsection 6\\(2.1\\)\]\(#\)](#);

**(12) Clause 18 (1) (g.6) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(13) Clause 18 (1) (h) of the Act is repealed.**

**(14) Clause 18 (1) (k) of the Act is repealed.**

**(15) Clause 18 (1) (k.1) of the Act is repealed and the following substituted:**

(k.1) respecting how drug benefit prices are to be calculated for the purposes of section 16;

**(16) Clause 18 (1) (k.2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(17) Clause 18 (1) (k.3) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(18) Subsection 18 (1) of the Act is amended by adding the following ~~clause~~[clauses](#):**

(k.5.1) clarifying the definition of "rebate" in section 11.5, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition and clarifying how the calculations are to be made in that section;

[\(k.5.2\) clarifying the records which may be examined by an inspector for the purposes of subsections 14\(2\) and 14\(3\);](#)

**(19) Clause 18 (1) (k.6) of the Act is repealed and the following substituted:**

(k.6) prescribing conditions under which the Minister and the executive officer may collect or use personal information under subsection 13 (1) or (2), conditions under which the Minister and the executive officer shall disclose personal information under subsection 13 (3) and conditions under which the Minister and the executive officer may enter into agreements under subsection 13 (4);

**(20) Clause 18 (1) (l) of the Act is repealed.**

**(21) Subsections 18 (1.1), (1.2) and (1.3) of the Act are repealed.**

**(22) Clause 18 (5) (d) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**28. Sections 19, 20, 21, 22 and 23 of the Act are repealed and the following substituted:**

#### **Decisions about listing, delisting**

**19.** In deciding whether or not to designate a drug product as a listed drug product or to remove such a designation, the executive officer may consider anything he or she considers advisable in

the public interest, including, without limiting the generality of the foregoing, the drug benefit price of the drug product or other drug products or the price charged to operators of pharmacies for the drug product or other drug products.

### **Delisting**

**20.** (1) The executive officer may remove a drug product's designation as a listed drug product even if none of the conditions prescribed under clause 18 (1) (b.1) are breached, if he or she considers it advisable in the public interest to do so.

### **Effect of breach of continuing conditions**

(2) Despite a breach of a condition prescribed under clause 18 (1) (b.1), a drug product does not cease to be a listed drug product until its designation as a listed drug product is removed.

### **Advisors**

**21.** The Minister, the executive officer or any body or official who advises the Minister, the executive officer or the Lieutenant Governor in Council with respect to anything under this Act may, in formulating such advice, consider anything the Minister, the executive officer or Lieutenant Governor in Council may consider.

### **Drug benefit price**

**22.** (1) The drug benefit price for a drug product when it becomes a listed drug product shall be the amount agreed to by the executive officer and the manufacturer, subject to any conditions that may be prescribed.

### **Executive officer's agreement**

(2) In deciding whether to agree to an amount under subsection (1), the executive officer may consider any matter the executive officer considers advisable in the public interest, including, without limiting the generality of the foregoing, the drug benefit price of other drug products or the price charged to operators of pharmacies for the drug product or other drug products.

### **Request for change**

(3) A manufacturer may request, in writing, that the executive officer change a drug benefit price, but the executive officer is not obligated to act on the request.

### **Criteria for requesting change**

(4) The executive officer may establish rules, criteria and procedures that must be followed by a manufacturer in submitting requests for changes in a drug benefit price, including providing for how often such requests may be made, and shall post those rules, criteria and procedures on the Ministry's website and in any other format the executive officer considers advisable.

### **Manufacturer must comply**

(5) A manufacturer that submits a request for a change in a drug benefit price shall comply with

the posted rules, criteria and procedures.

#### **Where conflict**

(6) In the event of a conflict between what is posted on the Ministry's website under subsection (4) and what is posted in another format, the Ministry's website prevails.

#### **Changing drug benefit price**

(7) Subject to any conditions that may be prescribed, the executive officer may change the drug benefit price of a drug product in consultation with the manufacturer if a request has been made under subsection (3) and the executive officer considers it to be in the public interest to make the change, and such a change is effective on the date that it is indicated in the Formulary as taking effect.

#### **Documentation**

(8) In determining whether a change in the drug benefit price is in the public interest, the executive officer may require the manufacturer to supply any information, other than personal information, that the executive officer considers relevant, and the manufacturer shall comply with the request.

#### **Transitional**

(9) The drug benefit price of a drug product that was a listed drug product immediately before October 1, 2006 shall be its drug benefit price as it existed under this Act at that time, until it is changed as permitted under this Act and the regulations.

#### **Clarification**

(10) For greater clarity, the executive officer may change the drug benefit price of any drug product that was listed in the Formulary that existed immediately before October 1, 2006, and that was referred to in the regulations made under this Act or the *Drug Interchangeability and Dispensing Fee Act*, but only as provided for in this Act or its regulations, or the *Drug Interchangeability and Dispensing Fee Act* and its regulations.

#### **Conditions of payment**

**23.** (1) The executive officer may require that, in respect of a specified drug product or class of drug products, specified clinical criteria must be met for the executive officer to pay an amount in respect of the supplying of that drug product or class of drug products for particular patients or a particular class of patients.

#### **Publication**

(2) Where the executive officer specifies anything under subsection (1), he or she shall publish it in the Formulary.

#### **Clinical criteria**

(3) Without limiting the generality of subsection (1), clinical criteria may include,

(a) considerations relating to the use or the possibility of the use of other drug products or therapies for particular patients or a particular class of patients;

(b) a requirement that the use of a drug product for particular patients or a particular class of patients require a prescription from a physician or member of a class of physicians specified by the executive officer;

(c) a requirement that a specified person or an expert panel recommend or approve the use of a drug product for particular patients or a particular class of patients.

#### **When clinical criteria not met**

(4) If an operator of a pharmacy supplies a drug product for an eligible person and, because of the criteria set under this section, the executive officer is not required to pay an amount in respect of that supply, the operator may charge or accept payment from a person other than the executive officer in an amount equal to the sum of,

(a) the amount the executive officer would have paid under this Act, absent the criteria; and

(b) the amount the operator could have charged under this Act, absent the criteria.

#### **Exception**

(5) Subsection (4) does not apply if, under section 16, the executive officer makes this Act apply in respect of the supplying of the drug product for the eligible person.

### **PART III COMMENCEMENT AND SHORT TITLE**

#### **Commencement**

**29. (1) Section 3, subsections 5 (2), 12 (3) and 27 (10), this section and section 30 come into force on the day this Act receives Royal Assent.**

#### **Same**

**(2) Sections 1, 2 and 4, subsections 5 (1), (3) and (4), sections 6 to 11, subsections 12 (1), (2), (3.1), (3.2), (4), (5) and (5.6), sections 13 to 26, subsections 27 (1) to (9) and (11) to (22) and section 28 come into force on October 1, 2006.**

#### **Short title**

**30. The short title of this Act is the *Transparent Drug System for Patients Act, 2006*.**

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